



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------|-------------|----------------------|---------------------|------------------|
| 10/577,296 | 04/28/2006 | Eitora Yamamura | 07200076001 | 9736 |
| 22511 | 7590 | 02/22/2008 | EXAMINER | |
| OSHA LIANG L.L.P. | | | MEAH, MOHAMMAD Y | |
| 1221 MCKINNEY STREET | | | ART UNIT | PAPER NUMBER |
| SUITE 2800 | | | 1652 | |
| HOUSTON, TX 77010 | | | | |
| NOTIFICATION DATE | | DELIVERY MODE | | |
| 02/22/2008 | | ELECTRONIC | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@oshaliang.com
buta@oshaliang.com

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/577,296 | YAMAMURA ET AL. |
| | Examiner | Art Unit |
| | MD. YOUNUS MEAH | 1652 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 30 November 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 4,6,7,10-26 and 29-36 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2,5,8,9,27 and 28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/ are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/28/08, 8/28/066
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) Notice of Informal Patent Application
- 6) Other: _____

DETAILED ACTION

Applicants' election with traverse of group 1 (claims 1-2, 5, 8-9 and 27-28) in their response of 11/30/2007 is acknowledged.

Election/Restriction

Applicant, on date 11/30/2007, elected traverse Group 1 (claims 1-2, 5, 8-9 and 27-28), drawn to DNA fragment comprising DNA replication region having Nucleotide sequence of SEQ ID NO:35 and vector having said DNA for examination. Groups 2-31 (claims 4, 6-7, 10-26 and 29-36) of election/restriction-office action of date 11/1/2007 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected Groups.

Applicants arguments of 1.) the international examiner found only 3 inventions not 31 inventions and 2.) The claims are linked by a unity of invention (via SEQ ID NO: 73 which is full length sequence of plasmid pRET1100) are answered as follows:

1. The traversal is on the ground(s) that in the international phase, international examiner found only 3 inventions not 31 inventions as there is a unity of inventions exit in all these polynucleotide molecules having various SEQ ID NOs. Applicant's arguments have been fully considered but are not deemed persuasive to withdraw the restriction requirement previously applied. With regard to the finding of unity of invention in the international phase, it is noted that even if the International Authority found unity of invention regarding the instant claims, according to 37 CFR 1.499, if the Examiner finds that a national stage application lacks unity of invention under 37 CFR 1.475, the Examiner may in an Office action require the applicant in the response to that action to elect an invention to which the claims shall be restricted. Such requirement may be made before any action on the merits but may be made at any time before

the final action at the discretion of the Examiner. Thus a finding of unity of invention in the international stage is not binding on the examination during national phase examination.

2 Applicants argument of the claims are linked by a unity inventions, especially claims 1-11, 17, 24 and 27-38, is not found persuasive because, although plasmid pRET1100 comprising SEQ ID NO: 73 may comprise DNA fragment of SEQ ID NO: 35, and other DNA fragments comprising SEQ ID NOs: 1-34, 36-37 and 76, these fragments may be present in many other plasmid or in other full length DNAs unrelated to SEQ ID NO: 73. Furthermore searching these large number of DNA molecules comprising SEQ ID NOs: 1-37 and 76 would be undue burden on the examiner. Usually USPTO restrict to search polynucleotide or protein molecule comprising **one** SEQ ID number. Therefore the restriction is maintained and made FINAL.

Priority

Acknowledgement is made of applicant's PCT priority date based on application filing date of 10/29/2004 # PCT/JP04/16104 and foreign application filing date 10/31/03 Japan 2003-373476.

Information Disclosure Statement

The information disclosure statements (IDS) submitted on 04/28/2006 and 8/28/2006 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the IDS statements.

Claim Objections

Claims 1-2, 5, 8-9 and 27-28 are objected for having non-elected subject matters.

Appropriate correction required.

Claim Rejections

35 U.S.C 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The claimed inventions in claims 1-2, 5, 8-9 and 27-28 are rejected under 35 USC 101 because the claimed invention directed to non-statutory subject matter. In the absence of the hand of man, naturally occurring DNA are non-statutory subject matter (Diamond v. Chakrabarty, 206 USPQ 193 (1980). The DNA fragment of these claims (SEQ ID NO: 35) are natural substance. Naturally occurring plasmid of *Rhodococcus erythropolis* IAM1400, IAM1503, JCM2893 and JCM2894 strains contain the DNA replicating region comprising said DNA fragment.

The rejection may be overcome by amending claims to recite wording such as an isolated or recombinant DNA.

Conclusion

Claims 1-2, 5, 8-9 and 27-28 are rejected and no claim is allowed.

Art Unit: 1652

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mohammad Meah whose telephone number is 571-272-1261. The examiner can normally be reached on 8:30-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mohammad Younus Meah, PhD
Examiner, Art Unit 1652
Recombinant Enzymes, 3C31 Remsen Bld
400 Dulany Street, Alexandria, VA 22314
Telephone: 517-272-1261